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| EXAMINER |
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MERTZ, PREMA MARIA

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1646
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24

Please find below and/or attached an Office communication concerning this application or proceeding.

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| Office Action Summary | Application No. 09/416,267 | Applicant(s) Su et al. |
| | Examiner Prema Mertz | Art Unit 1646 |
| <i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i> | | |
| Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. <ul style="list-style-type: none"> - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | |
| Status <p>1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>May 9, 2003</u></p> <p>2a) <input type="checkbox"/> This action is FINAL. 2b) <input checked="" type="checkbox"/> This action is non-final.</p> <p>3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11; 453 O.G. 213.</p> | | |
| Disposition of Claims <p>4) <input checked="" type="checkbox"/> Claim(s) <u>25-79</u> is/are pending in the application.</p> <p>4a) Of the above, claim(s) _____ is/are withdrawn from consideration.</p> <p>5) <input type="checkbox"/> Claim(s) _____ is/are allowed.</p> <p>6) <input checked="" type="checkbox"/> Claim(s) <u>25-79</u> is/are rejected.</p> <p>7) <input type="checkbox"/> Claim(s) _____ is/are objected to.</p> <p>8) <input type="checkbox"/> Claims _____ are subject to restriction and/or election requirement.</p> | | |
| Application Papers <p>9) <input type="checkbox"/> The specification is objected to by the Examiner.</p> <p>10) <input type="checkbox"/> The drawing(s) filed on _____ is/are a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).</p> <p>11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action.</p> <p>12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.</p> | | |
| Priority under 35 U.S.C. §§ 119 and 120 <p>13) <input type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</p> <p>a) <input type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of:</p> <ol style="list-style-type: none"> 1. <input type="checkbox"/> Certified copies of the priority documents have been received. 2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____. 3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). <p>*See the attached detailed Office action for a list of the certified copies not received.</p> <p>14) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.</p> <p>15) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.</p> | | |
| Attachment(s) <p>1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). <u>21</u></p> <p>4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>6) <input type="checkbox"/> Other: _____</p> | | |

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DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/9/03 has been entered.

2. Claims 1-24 have been canceled. Claims 25-79 are pending in the instant application.

Claim rejections-35 U.S.C. 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25-79 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

This rejection is maintained for reasons of record set forth at pages 3-5 of the previous Office action (Paper No. 10, 9/7/00), pages 2-6 of the previous Office action (Paper No. 13,

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5/8/01), pages 2-8 of the previous Office action (Paper No. 18, 9/16/02) and pages 2-5 of the previous Office action (Paper No. 20, 2/10/03).

The instant claims are drawn to a polypeptide which has an as yet undetermined function or biological significance. Until some actual and specific significance can be attributed to the protein identified in the specification as having homology to "Tsg" (page 2, lines 10-17), the instant invention is incomplete. The instant protein shares less than 30% sequence homology with the "Tsg" protein (see Figure 2) which Tsg protein modulates morphogenetic effects of decapentaplegic (dpp) and its orthologs, the bone morphogenetic proteins 2 and 4 (BMP2/4), in early Drosophila and vertebrate embryos. However, the instant specification does not disclose any information regarding functional characteristics or the biological activity of the instantly claimed protein other than it may stimulate cell proliferation and/or differentiation and may be used to treat, restenosis and inflammation (page 3, lines 5-8). There is no guidance given about which specific activity/activities the claimed polypeptide would be likely to have. The specification does not demonstrate that the claimed polypeptide actually displays any of these recited activities. In the absence of knowledge of the specific biological significance of the claimed protein, there is no immediately obvious patentable use for it. Since the instant specification does not disclose a "real world" use for the nucleic acid encoding the protein then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 USC § 101 as being useful.

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Applicants disclose in the specification that the claimed protein has homology to the “Tsg” protein (page 2, lines 11-17). The state of the art is such that functional information can be automatically derived from structural information only to a limited extent, (see Sklonick et al, Nature Biotechnology, Vol.18, No.3, pages 283-287, especially page 286, middle of column 1). Sklonick et al also state that knowledge of the overall structure or domain family is still not enough to confidently assign function to a protein. Therefore, there is little doubt that, after further characterization, the protein is found to be member of the cytokine family, the claimed protein would have a specific, substantial and credible utility. However, further characterization is part of the invention and until it had been undertaken, the claimed invention is not supported by a specific asserted utility or a well established utility. The claimed invention is directed to a polypeptide of as yet undetermined function or biological significance. Thus, the invention is not supported by either a specific and substantially asserted utility or a well established utility.

Applicants argue that a rejection under 35 USC § 101 is proper when a person of ordinary skill in the art would find credible disclosed features or characteristics of the invention, or statements made by the applicant in the written description of the invention. Furthermore, Applicants argue that they need only make one credible assertion of utility for the claimed invention to satisfy 35 USC § 101. However, contrary to Applicants arguments, simply asserting that the instant protein may stimulate cell proliferation and/or differentiation and may be used to treat, restenosis and inflammation (page 3, lines 5-8) is not a specific or substantial utility for the reasons argued below.

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Firstly, the specification recites “cell proliferation and/or differentiation” and there is no further disclosure in the specification whether the instant polypeptide has either of these specific activities or both. Secondly, the specification recites “may be employed to treat and/or prevent restenosis and inflammation” indicating the possibility that the polypeptide may be used for these conditions but the specification fails to provide any further disclosure about the use of the polypeptide in the treatment of any of these conditions. Applicant is only required to identify one substantial credible utility and the employment of this protein only as the subject of further research does not satisfy the utility requirement of 35 U.S.C. § 101 because the courts have interpreted this statute as requiring an invention to have “substantial utility” “where specific benefit exists in currently available form”. The possibility of the employment of a protein of the instant invention to treat inflammation is not a substantial or specific utility.

Applicants have cited the Graf et al. (2202) publication showing that the Tsg protein modulates BMP2/4 in early Drosophila and vertebrate embryos (see abstract, lines 1-3). Firstly, the Graf reference was published in 2002, six years after the earliest filing date of the instant application. Applicants are reminded that an invention must be complete as filed. The disclosure of the reference is evidence that the instant invention is not useful in currently available form because the instant protein has not been used in a manner that discloses that the function of the instant protein can be foretold with certainty.

Secondly, the publication demonstrates that Tsg affects the binding of dpp/BMP2/4 to their cellular receptors and downstream signaling events mediated by the phosphorylation,

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nuclear translocation, and transcriptional activity of Smad proteins positively or negatively (see page 164, column 1, entire first para). Furthermore, the Graf reference discloses that the study of Tsg is currently limited to early embryonic development (see page 164, column 1, last 5 lines of first para). The reference discloses the natural role of Tsg in the thymus (see abstract), however, the instant specification there is not even a hint of such a role for the instant protein.

Additionally, the reference discloses nothing about Tsg being a cytokine, however, the reference discloses that Tsg modulates other cytokines like BMP2/4 (see abstract). According to the Graf reference, the only time Tsg has an effect is during embryogenesis and in the thymus, however, the instant application fails to even give a hint of what is disclosed in the reference. Page 169, column 2 of the reference, discloses that the relative abundance of Tsg and chordin can be critical for whether Tsg acts as an agonist or an antagonist of dpp/BMP2/4 and Tsg synergized with chordin to antagonize BMP4 in a simple, dose-dependent manner (Figure 5). Therefore, the reference discloses the ability of Tsg to act as an antagonist, however, there is no such disclosure of any kind for the polypeptide of the instant invention.

Applicants argue that all that is required of applicants is that there be a reasonable correlation between the biological activity and the asserted utility. However, contrary to Applicants arguments, as argued above, the specification describes only vague and hypothetical uses for the claimed protein. The present specification only presents an invitation to further characterize the claimed invention and to identify practical uses for the protein providing only vague guidance as to where or how such efforts should be directed. The courts have held that it

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cannot be presumed that a chemical compound is "useful" under § 101, or that one of skill in the art will know "how to use" it, simply because the compound is closely related only in a structural sense to other compounds known to be useful. Also, that nebulous descriptions of biological properties or activities of a compound in a specification do not convey an explicit indication of the usefulness of the compound and how to use them. Furthermore, it is not enough that the specification disclose that an intermediate can be used to produce some intended product of no known use. Nor is it enough that the product disclosed to be obtained from the intermediate belongs to some class of compounds which now is, or in the future might be, the subject of research to determine some specific use. See *In re Kirk*, 153 USPQ 48 (CCPA 1967). The Court has ruled that where the sole utility for an invention is further research on itself, whether as an object of scientific inquiry or to determine a practical use, the invention does not meet the requirements of 35 USC 101. *Brenner v. Manson*, 148 USPQ 689, 695-696 (US 1966).

Claims 25-79 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantially asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The instant specification fails to disclose a specific and substantial asserted utility or well established for the claimed protein. The fact that the claimed protein has about 30% homology to the Tsg protein is not sufficient to establish a specific and substantially asserted utility or a well established utility for it.

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Conclusion

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 305-3014 or (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 746-5300.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Prema Mertz
Prema Mertz Ph.D.
Primary Examiner
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June 26, 2003